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10/566,329

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EXAMINER

FORMAN, BETTY J

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/566,329	<b>Applicant(s)</b> XIAN ET AL.	
	<b>Examiner</b> BJ Forman	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/09, 3/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, Claims 1-30 and 55 in the reply filed on 30 July 2010 is acknowledged.

Claims 31-54 and 56-58 are canceled.

Claims 1-30 and 55 are pending and under prosecution.

### ***Claim Objections***

Claims 8 and 12 are objected to because of the following informalities: "identical" is misspelled "dential".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-30 and 55 rejected under 35 U.S.C. 102(e) as being anticipated by Xing et al (U.S. Patent No. 7,767,438, filed 28 March 2003).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claims 1-30 and 55, all the element of the instant claims are taught and/or claimed in the '438 patent. The patent claims differ from the instantly claimed device in that the patent claims are further drawn to a microarray chip having projections in addition to the instantly claimed cover having projections. However, the additional projections of the patent are encompassed by the open claim language "comprising" of the instant claims. Therefore, the '438 patent anticipates the device as instantly claimed.

Claims 1-3, 5, 11-13, 19-24, 30 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Stuelpnagel et al (WO 02/000336, published 3 January 2002).

Regarding Claim 1, Stuelpnagel teaches a microarray device having a plurality of microarray areas (45) and a cover (10) having a plurality of projections wherein a plurality of microarray reaction spaces (45) are formed between the chip and projections and wherein the volumes of the reaction spaces are identical and controllable by the

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height of the cover and projections (page 7, lines 18-28, page 13, lines 13-24, page 19, lines 4-9 and Fig. 1A).

Regarding Claim 2, Stuelpnagel teaches the microarray chip is a slide (page 12, line 24)

Regarding Claim 3, Stuelpnagel teaches the device further comprising an enclosure to from a plurality of separated microarray areas and reaction spaces (i.e. hybridization chamber, page 19, lines 4-9 and Fig. 7).

Regarding Claim 5, Stuelpnagel teaches the device wherein the enclosure has a rectangular shape (i.e. microtiter plate, page 19, lines 23-28 and Fig. 7).

Regarding Claim 11, Stuelpnagel teaches the device wherein the number of projections and/or microarray areas are between 2 and 2500 (i.e. microtiter plate, page 12, lines 25-28 and page 19, lines 23-28).

Regarding Claim 12, Stuelpnagel teaches the device wherein the number of projections and microarray areas are the same (page 16, lines 9-16).

Regarding Claim 13, Stuelpnagel teaches the device wherein the projections and microarray areas have the same shapes i.e. the projections have the same shape and the microarray areas formed in the microtiter plate have the same shape (page 13, lines 13-24, page 19, lines 4-9 and Fig. 1A). Stuelpnagel teaches the projections have a shape (e.g. "stick") that differs from the reaction areas (e.g. well) (page 17, lines 6-17).

Regarding Claim 19, Stuelpnagel teaches the device wherein the substrate comprises silicon, plastic, glass, ceramic, metal or a polymer (page 12, lines 4-14).

Regarding Claims 20-21, Stuelpnagel teaches the device wherein the cover comprises plastic (page 20, lines 3-6). While the reference is silent regarding injection molding, absent evidence to the contrary, the claimed process for making the cover does distinguish the cover made by another method.

The courts have stated that “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Regarding Claim 22, Stuelpnagel teaches the cover comprises plastics as described for the substrate (page 20, lines 3-6) which they define as e.g. polypropylene (page 12, lines 8-13).

Regarding Claims 23-24, Stuelpnagel teaches the device wherein the cover comprises glass (page 20, lines 3-6). While the reference is silent regarding injection the methods of Claim 24, absent evidence to the contrary, the claimed process for making the cover does distinguish the cover made by another method.

Regarding Claim 30, Stuelpnagel teaches the device wherein a reactant (i.e. bioactive agent) is immobilized in the array area (page 8, lines 22-27)

Regarding Claim 55, Stuelpnagel teaches a microarray device having a microarray areas (45) and a cover (10) having a projection wherein a microarray

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reaction space (45) is formed between the chip and projection and wherein the volume of the reaction space is controllable by the height of the cover and projection (page 13, lines 13-24, page 19, lines 4-9 and Fig. 1A).

Claims 1-24, 30 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Webb et al (U.S. Patent No. 7,332,328, filed 6 September 2002).

Regarding Claim 1, Webb teaches a microarray device having a plurality of microarray areas (6) and a cover (12) having a plurality of projections (3) wherein a plurality of microarray reaction spaces are formed between the chip and projections and wherein the volumes of the reaction spaces are identical and controllable by the height of the cover and projections (Column 3, lines 4-23, Column 12, line 60-Column 13, line 5 and Fig. 3A/B). It is noted that Webb teaches that microarrays are formed on the projections and/or bottom of wells.

Regarding Claim 2, Webb teaches the device wherein the chip is a glass slide (Example 2, Column 20, line 7).

Regarding Claims 3-4, Webb teaches the device further comprising an enclosure to from a plurality of separated microarray areas and reaction spaces (i.e. a gap comprising the projections and microarray reaction area formed between the cover and substrate wherein the gap is 175  $\mu\text{m}$ , Example 2, Column 20, lines 4-10) which is within the claimed range of 0.05 to 50mm.

Regarding Claim 5, Webb teaches the device wherein the enclosure has a round shape (Example 2 and Fig. 17A).

Regarding Claim 6, Webb teaches the device wherein the cover has a through hole (50) for fluid delivery (Column 12, lines 32-54).

Regarding Claim 7, Webb teaches the device wherein each projection has 1-6 through holes (Column 12, lines 49-54). The 96-well plate having 1-6 through holes is encompassed by the claimed range of 1 to 2,500.

Regarding Claim 8, Webb teaches the projections have 1-6 through holes. The claim defines identical or different number of projections and through hole. The instantly claimed identical or different number encompasses any number of through holes per projection. Therefore, Webb anticipates the instantly claimed device.

Regarding Claims 9-10, Webb teaches the through hole has a circular shape i.e. cross-sectional diameter of 500  $\mu\text{m}$  (Column 12, lines 45-46).

Regarding Claim 11, Webb teaches the device wherein the number of projections and/or microarray areas are between 2 and 2500 (i.e. a standard 96, 384 or 1536-well plate microtiter plate, Column 8, lines 30-43).

Regarding Claim 12, Webb teaches the device wherein the number of projections and microarray areas are the same (Fig. 3 and 6). The claim defines identical or different number of projections and microarray areas. The instantly claimed identical or different number encompasses any number of through holes per projection. Therefore, Webb anticipates the instantly claimed device.



Regarding Claim 13, Webb teaches the device wherein the projections and microarray areas have the same shapes i.e. the projections have the same shape and the microarray areas formed by the microtiter plate have the same shape (Column 8, lines 30-60, Column 10, lines 18-54 and Fig. 3 & 6).

Regarding Claim 14, Webb teaches a gap area formed between the cover and substrate comprising the projections and microarray reaction areas wherein the gap is 175  $\mu\text{m}$  (Example 2, Column 20, lines 4-10). Hence, the projections are within the claimed range of 0.01 to 50mm.

Regarding Claim 15, Webb teaches the device wherein the projections have a shape selected from square and circle (Fig. 2).

Regarding Claim 16, Webb teaches the device wherein the surface of the projections has an area of 10-250 microns (Column 14, lines 63-65) which is within the claimed range of 0.01 to 600  $\text{mm}^2$

Regarding Claim 17, Webb teaches the device wherein a gap comprising the projections and microarray reaction area is formed between the cover and substrate wherein the gap is 175  $\mu\text{m}$  (Example 2, Column 20, lines 4-10) which is within the claimed range of 0.001 to 1mm.

Regarding Claim 18, Webb teaches the device wherein the reaction volume is 9 (Example 2, Table 4) which is within the claimed range of 0.01 to 600  $\text{mm}^2$ .

Regarding Claim 19, Webb teaches the device wherein the substrate comprises glass, metal or plastic (Column 14, lines 33-55).

Regarding Claims 20-21, Webb teaches the device wherein the cover comprises plastic (Column 14, lines 33-36). The reference further teaches injection molding (Column 13, lines 19-21). However, it is noted that, absent evidence to the contrary, the claimed process for making the cover does distinguish the cover made by another method.

Regarding Claim 22, Webb teaches the cover comprises polypropylene or polystyrene (Column 13, lines 54-58).

Regarding Claims 23-24, Webb teaches the device wherein the cover comprises glass (Column 13, lines 13-63). The reference further teaches that the projections are provided by sliced-array techniques (Column 9, lines 49-65). However, absent evidence to the contrary, the claimed process for making the cover does distinguish the cover made by another method.

Regarding Claim 30, Webb teaches the device wherein a reactant (i.e. probe) is immobilized in the array area (Column 3, lines 4-23).

Regarding Claim 55, Webb teaches a microarray device having a microarray area (6) and a cover (12) having a projection (3) wherein a microarray reaction space is formed between the chip and projection and wherein the volume of the reaction space is controllable by the height of the cover and projection (Column 3, lines 4-23, Column 12, line 60-Column 13, line 5 and Fig. 3A/B).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al (U.S. Patent No. 7,332,328, filed 6 September 2002) in view of MacBeath et al (U.S. Patent No. 7,063,979, filed 13 June 2002).

Regarding Claims 25-29, Webb teaches the device wherein the microarray reaction areas are formed using silicone chambers (Example 2, Column 20, lines 4-10) but the reference is silent regarding double-sided tape.

However, silicone/rubber chambers for forming reaction chambers were known to use adhesive tape (e.g. double-sided and/or compressable material treated for adhesion) for forming water-tight seals as taught by MacBeath (Column 8, lines 55-67 and Column 17, lines 18-50). MacBeath teaches the device wherein the treated gaskets provide the chambers with a watertight seal between the gasket and the microarray thereby preventing cross-contamination between the wells/chambers (Column 6, line 53-Column 7, line 20). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the silicone chamber of Webb by adding the double-sided tape adhesive of MacBeath. One of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, for the benefit of providing a water-tight seal between the

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wells/chamber thereby preventing cross-contamination as taught by MacBeath (Column 6, lines 53-67).

Claims 26 and 28 define methods for making the enclosure by stamping. However, as noted above, the courts have stated that a process for making a device does not define the device over a prior art device made by another method. Therefore the instantly claimed stamping does not patentably distinguish the device.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-30 and 55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 7,767,438. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a device comprising a cover having projections and a microarray chip wherein microarray areas are formed between the projections and chip. The claim sets differ in that the patent claims are further drawn to projections on the microarray chip in addition to the instantly claimed cover having projections. However, the additional projections of the patent are encompassed by the open claim language "comprising" of the instant claims. Therefore, the instantly claimed device is not patentably distinct from the '438 patent.

### ***Conclusion***

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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